



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/287,884	04/07/1999	HAROLD J. WANEBO	58463/JPW/EM	6824

7590

01/27/2005

JOHN P WHITE
COOPER & DUNHAM
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER

LEWIS, AMY A

ART UNIT	PAPER NUMBER
----------	--------------

1614

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 09/287,884	Applicant(s) WANEBO ET AL.	
	Examiner Amy A. Lewis	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>June 18, 2004</u> . | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
6) <input type="checkbox"/> Other: _____. |
|---|--|

DETAILED ACTION

Claims 20-33 are presented for examination.

Status of the Case

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 18 June 2004 has been entered.

The Supplemental Information Disclosure Statement, filed 18 June 2004, has been entered into the application.

Amendments To the Specification

The amendment to the specification filed 24 May 2004 has been entered into the application.

Amendments To the Claims

No amendments to the claims are made in the 24 May 2004 amendment/response. Consequently, claims 20-33 are present and examined.

Information Disclosure Statement

The information disclosure statement filed 18 Jun 2004 has been received, entered into the application file, and considered. An annotated copy is attached to this Office Action.

Taxol is the trade name for paclitaxel. The term paclitaxel will be used in this office action and is considered to be the same as Taxol.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1) Claims 20 and 21 are rejected under 35 U.S.C. 102(a) as being anticipated by Myrick et al. ("Taxol and ceramide act synergistically in the growth inhibition of Jurkat, a leukemic T-cell line," *FASB Journal*, vol. 11, no. 2, p. A546 (Abstract 3157, 1997)), referred to as Abstract A546

Art Unit: 1614

hereafter. A546 was provided by Applicants on PTO-1449, dated 18 June 2004, and is available as prior art with a date of 1997.

The Myrick et al. Abstract A546 teaches that treatment of Jurkat T-cells, a leukemic cell line, with paclitaxel and ceramide results in 87% growth inhibition through cell cycle arrest and apoptosis. Abstract A546 also teaches the addition of paclitaxel followed by ceramide as well as the reverse.

2) Claims 20, 22, 23, 24, 25, 27, 28, 29, 30, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Joshi et al. (US Patent 6,841,537 B1) which claims benefit to provisional application 60/11637, filed on 9 December 1998. Joshi et al. teaches a method of cancer therapy where the cancer cells are transformed with nucleic acids that encode gene products to inhibit growth of the cancer cells (abstract). The method includes administering to a cancer patient a nucleic acid (also referred to as a foreign therapeutic gene) that transforms the cancer cells and inhibits their growth by inducing apoptosis; and further administering paclitaxel as a cell cycle synchronizer to enhance the effect of the foreign therapeutic gene ('537 claims 1, 8, 9, 15, 16, 22, and 23).

Specific claim limitations are addressed below in subsections 2a-2c:

2a) In addition, the paclitaxel is in a liposomal formulation of instant claims 23 and 29, of which ceramide is listed as an example (specification col. 7, line 64; claims 9 and 23).

2b) Joshi et al. teach the administration techniques of instant claims 24 and 29 at col. 16, lines 60+ of the specification, including intravenous injection.

Art Unit: 1614

2c) Joshi et al. teach the treatment of human colon adenocarcinoma, human ovarian carcinoma, mouse melanoma, lung carcinoma, of the Markush groups of claims 20, 25, 30, and 31 (specification p. 16 lines 21-28).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1) Claims 20, 25, 26, 30, and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jayadev, et al. in view of Mycek, et al., U.S. Patent Nos. 5,597,830 and 6,147,060.

Jayadev, et al. ("Role for Ceramide in Cell Cycle Arrest," (1995) *J Biological Chemistry*, Vol. 270, No. 5, p. 2047-2052) teach that ceramide causes significant arrest in the G₀/G₁ phase, with pronounced apoptosis, in Molt-4 leukemia cells (Abstract). Jayadev does not teach treatment with paclitaxel.

Mycek, et al. (*Lippincott's Illustrated Review: Pharmacology* 2nd ed., p. 376, 392) teach that paclitaxel blocks mitosis in the G₂-M phase by reversibly binding to tubulin, stabilizing the microtubules, causing the cells to remain in metaphase, and thereby causing cell death. Mycek, et al. does not teach treatment with ceramide.

It is known in the field of cancer chemotherapy that combination chemotherapy is more effective than single-drug treatment in most cancers for which chemotherapy is effective. Cytotoxic agents with different molecular sites and mechanisms of action are usually combined at full doses, resulting in better response rates. (See Mycek, et al., *Lippincott's Illustrated Review: Pharmacology* 2nd ed., p. 376). In addition, U.S. Patent Nos. 5,597,830 and 6,147,060 teach combination chemotherapy for cancer using multiple drugs.

The teaching of combinatorial chemotherapy ('830 and '060 patents) in cancer treatment would have motivated one of ordinary skill in the art to have used the two drugs for their known modes of action in the cell cycle to effect the desired treatment of the cancer at multiple levels. It would have been obvious to one of ordinary skill in the art of cancer treatment to combine paclitaxel and ceramide (both known to treat cancer) since they work at different times during the cell cycle.

Summary

Myrick et al. "Paclitaxel-induced apoptosis in Jurkat, a leukemic T-cell, is enhanced by ceramide," *FASB Journal*, vol. 13, no. 4, Part 1, p. A191 (Abstract 177.2, March 12, 1999), also provided by Applicants on PTO-1449, is viewed as an equivalent teaching to Abstract A546.

Claims 20-33 are rejected. No claims are allowed.

Art Unit: 1614

Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is (571) 272-2765. The examiner can normally be reached on Monday-Friday, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy A. Lewis
Patent Examiner
Art Unit 1614

Chris Low S.F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800